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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/678,743

10/03/2003

James Dobbie

2785-1-001PCT CIP

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/678,743	Applicant(s) DOBBIE, JAMES	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-10,12-21,34-37 and 40-59 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,19,21,34,36 and 47-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8-10,12-18, 20, 35, 37,40-46 and 56-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) ☐ Other: ____. |

DETAILED ACTION

The RCE dated 8-22-08 is acknowledged.

Claims pending in the application are 1-10, 12-21, 34-37 and 41-59.

Applicant in response (4-30-07) to the restriction requirement dated 3-27-07 elected the species of method of treating surgical adhesions. Claims 7, 21, 36 which are drawn to clots were inadvertently included in the previous actions and thus withdrawn in the present action. Claims 5, 7, 19, 21, 34, 36 and 47-55 thus are withdrawn from consideration.

Claims included in the prosecution are 1-4, 6, 8-10, 12-18, 20, 35, 37, 40-46 and 56-59.

The examiner indicated to the attorney David Smith on 11-5-08 that the composition claims are allowable and the attorney agreed to the cancellation of the method claims.

However, in view of the following new reference, the following office action is being issued.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 8, 12-13, 16 and 56-59 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/72277 of record or applicant's statements of prior art.

WO teaches liposome compositions containing phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phosphatidyl inositol and

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cholesterol in claimed amounts (pages 5, 6, 15-17 and claims, 7 and 9 in particular).

The intended use has no significance in the composition claims.

Applicant on page 23 of the specification indicates that the lamellar bodies are present in many tissues throughout the body. Therefore, they are naturally occurring.

The 102 (b) rejection will be withdrawn upon determining the support in the priority paper (GB).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6, 8-10, 12-18, 20, 35, 37, 40-46, 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/72277 cited above in combination with WO 91/12026 of record or vice versa optionally in further combination with Szoka (5,077,057) and Sheffield et al (4,937,254).

WO teaches liposome compositions containing phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phosphatidyl inositol and cholesterol in claimed amounts (pages 5, 6, 15-17 and claims, 7 and 9 in particular).

WO 01 however, does not teach the use of the lamellar bodies for surgical adhesions.

WO teaches a method of reducing surgical adhesions by coating tissue surfaces

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with phospholipids. According to WO lecithin in combination with phospholipids such as phosphatidylethanolamine, phosphatidyl inositol, phosphatidylserine and sphingomyelin. Further according to WO less pure phospholipid could be used since certain impurities may act synergistically. These phospholipids include phosphatidylethanolamine, phosphatidyl inositol, phosphatidylserine, phosphatidyl glycerides (lyso phosphatides) and sphingomyelin. The compositions further contain hyaluronic acid. The compositions can be in the form of gels, pastes, solutions and sprays (abstract and pages 6, 8-9). Although WO does not explicitly state the compositions are in the form of lamellar bodies (liposomes), according to pages 5 and 6, the phospholipid is suspended in hyaluronic acid solution and sonicated and since the method of liposomes involves the hydration of the phospholipid with an aqueous medium, it would have been obvious to one of ordinary skill in the art that the composition taught by WO is a lamellar composition. Although WO does not teach the proportions of individual phospholipids in the mixture, it does teach the amount to be effective in the treatment of adhesions. Therefore, it would have been obvious to one of ordinary skill in the art to use appropriate amounts of individual phospholipids to obtain the desired synergistic effect based on the teachings of WO. Furthermore, lecithin in the art is known to contain phosphatidylethanolamine, phosphatidyl inositol, phosphatidylserine, phosphatidyl glycerides (lyso phosphatides) and sphingomyelin and their proportions vary according to the source such as egg or soybean. Therefore, one of ordinary skill in the art would be motivated to use commercial lecithin in combination with the other phospholipids taught by WO with a reasonable expectation of success. The examiner has already

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cited WO 95/08986 in this context (see Table A on page 4). One of ordinary skill in the art would be motivated to use instant amounts with a reasonable expectation of success since WO 01 teaches phospholipid composition containing instant amounts. One of ordinary skill in the art would be motivated to use WO 01 compositions for surgical adhesions since WO 91 teaches that phospholipid compositions can be used for the prevention of surgical adhesions. The criticality of number of liposomes is unclear since phospholipid amounts are important since they are the active agents and therefore, one of ordinary skill in the art would be motivated to estimate the number of liposomes containing the effective amounts of the phospholipids. In the absence of showing unexpected results, the protocol of administration (30 minutes intervals) is deemed to be an obvious parameter manipulated by an artisan to obtain the best possible results. It should be pointed out that WO on page 6 teaches that the phospholipid suspension may be applied and then re-applied at regular intervals.

Szoka teaches that the inclusion of cholesterol in liposomes increases the rigidity of the liposomes (col. 1, lines 25-37). Szoka further teaches the encapsulation of chemotherapeutic agents such as cis-platin (example 4).

Sheffield et al teach a method of inhibiting post-surgical adhesions by the topical administration of liposomes. The liposomes contain phosphatidylcholine and cholesterol. The compositions further include hyaluronic acid. The method of preparation involves the addition of an aqueous medium to the phospholipids (examples 13-19).

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The inclusion of cholesterol in the compositions of WO would have been obvious to one of ordinary skill in the art since the inclusion of cholesterol would rigidify the membranes of the lamellar bodies (liposomes). It would have been obvious to one of ordinary skill in the art that the preparations taught by WO could be in the form of liposomes since the reference of Sheffield shows that liposomes are formed by the addition of an aqueous medium to the phospholipids. The addition of cholesterol would have been obvious to one of ordinary skill in the art since cholesterol is added routinely to the liposomes when used for surgical adhesions. Although, the references do not teach the inclusion of anti-estrogen or a chemotherapeutic agent in the composition, since the adhesions are formed after surgery, and if the surgery is to remove an estrogen dependent tumor, it would have been obvious to one of ordinary skill in the art to use an anti-estrogen in the composition to treat any tumor cells left after surgery. Similarly, one of ordinary skill in the art would be motivated to include other chemotherapeutic agents in the composition if the tumor removed is not dependent on estrogen especially in view of Szoka which teaches the encapsulation of cis-platin.

4. Claims 16-18 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/72277 cited above in combination with WO 91/12026 of record or vice versa optionally in further combination with Szoka (5,077,057) and Sheffield et al (4,937,254) as set forth above, further in view of Vournakis (5,624,679).

The teachings of WO 01, 91, Szoka and Sheffield have been discussed above. As pointed out above, these references lack the teachings of use of an anti-estrogens and chemotherapeutic agents.

Vournakis while disclosing poly-acetylgalactosamine anti-adhesion compositions teaches that chemotherapeutic agents and anti-estrogens (tamoxifen) can be included in the compositions. Vournakis is further suggestive of the use of liposomes (abstract, col. 26, lines 52-54; col. 27, line 59 through col. 28, line 43; Examples 17-23).

The inclusion of anti-estrogens or chemotherapeutic agents in the compositions of WO 01, 91, Szoka and Sheffield would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Vournakis shows the routine use of anti-adhesive compound and the therapeutically active agent together.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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6. Claims 1-4, 6, 8-10, 12-18, 20, 35, 37, 40-46, 56-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/827,172. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are drawn to the same composition claimed in the copending application and a method of using the same composition in the said copending application. Instant composition which is recited as a combination of specific lipid (same as in claim 2 of the copending application) is a species of the composition in claim 1 of the copending application and therefore, anticipated by the claims in the copending application. Since phospholipids are known as the adhesion inhibitors as evident from the cited prior art, instant method claims are deemed to be obvious over the composition claims in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant submits their willingness to file a terminal disclaimer. The rejection is maintained in abeyance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK